service, or product failure, to be hazardous;

(2) The products are produced in small quantities;

(3) The products are used by trained individuals and are to be used by the same manufacturing corporation or for research, investigation, or training.

(4) The products are custom designed and used by trained individuals knowledgeable of the hazards; or

(5) The products are produced in such a way that the requirements are inappropriate or unnecessary.

(b) The Director may, subject to any conditions that the Director deems necessary to protect the public health, exempt manufacturers from all or part of the record and reporting requirements of this part on the basis of information submitted in accordance with paragraph (a) of this section or such other information which the Director may possess if the Director determines that such exemption is in keeping with the purposes of the Act.

(c) The Director will provide written notification of the reason for any denial. If the exemption is granted, the Director will provide written notification of:

(1) The electronic product or products for which the exemption has been granted;

(2) The requirements from which the product is exempted; and

(3) Such conditions as are deemed necessary to protect the public health and safety. Copies of exemptions shall be available upon request from the Food and Drug Administration, Center for Devices and Radiological Health, Division of Mammography Quality and Radiation Programs, 10903 New Hampshire Ave., Bldg. 66, rm. 4521, Silver Spring, MD 20993–0002.

(d) The Director may, on the Director's own motion, exempt certain classes of products from the reporting requirements listed in table 1 of §1002.1, provided that the Director finds that such exemption is in keeping with the purposes of the act.

(e) Manufacturers of products for which there is no applicable performance standard under parts 1020 through 1050 of this chapter and for which an investigational device exemption has been approved under §812.30 of this chapter or for which a premarket approval application has been approved in accordance with §814.44(d) of this chapter are exempt from submitting all reports listed in table 1 of §1002.1.

[60 FR 48387, Sept. 19, 1995, as amended at 72 FR 17401, Apr. 9, 2007; 75 FR 20916, Apr. 22, 2010]

§1002.51 Exemptions for manufacturers of products intended for the U.S. Government.

Upon application therefor by the manufacturer, the Director, Center for Devices and Radiological Health, may exempt from the provisions of this part a manufacturer of any electronic product intended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

[38 FR 28625, Oct. 15, 1973, as amended at 53 FR 11254, Apr. 6, 1988]

PART 1003—NOTIFICATION OF DEFECTS OR FAILURE TO COMPLY

Subpart A—General Provisions

Subpart B—Discovery of Defect or Failure To Comply

Subpart C—Notification

Subpart D—Exemptions from Notification Requirements